Office of Nonprescription Products
Program Description

Division of Nonprescription Regulation Development

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in determining the safety and efficacy of over-the-counter (OTC) drug products. This rotation will also offer experience in providing an overview of FDA's drug development, review, and post-marketing surveillance of prescription and non-prescription drug products.

I. Learning Objectives: Upon completion of this rotation, the student will be able to:

1. Describe FDA's role in the regulatory and administrative approval process of OTC drug products.
2. Distinguish between OTC drug products that are marketed under a new drug application (NDA) versus the monograph system.
3. Discuss the OTC drug review and monograph development.
4. Knowledgeable of key legal and drug regulatory statues that affect OTC drug products.
5. Outline the OTC drug monograph labeling requirements.
6. Become familiar with health literacy issues as related to OTC drug products as well as written formats of consumer-friendly medication information (i.e. medication guides).
7. Utilize ONP and FDA resources such as CDER guidance documents, Federal Register, DailyMed, Drugs@FDA, Electronic Orange Book, PubMed, Micromedex, and the Unified Agenda.
8. Answer questions with the laws, regulations, and guidance documents governing drugs.
9. Answer drug information request.

II. Student Requirements:

1. Be familiar with current drug news in the media and provide weekly summary reports.
2. Give a 30 min presentation with a minimum of 3-presentation learning objects and 5- review questions or conduct a project assigned by preceptor.
3. Draft a "Drug Facts Label" for a OTC monograph drug product.
4. Attend FDA's Pharmacy Student Lecture Series within the Office of the Commissioner and the Center for Drug Evaluation and Research.
5. Fulfill required hours.